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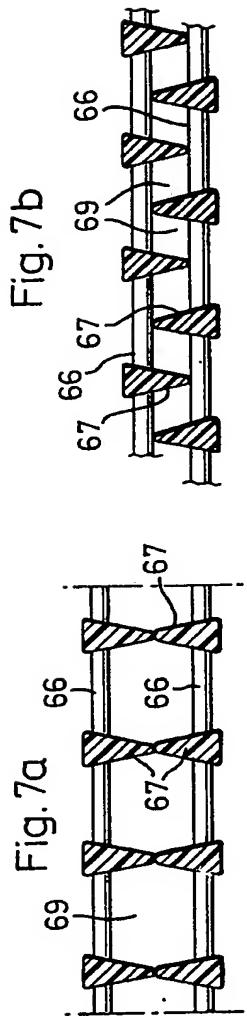
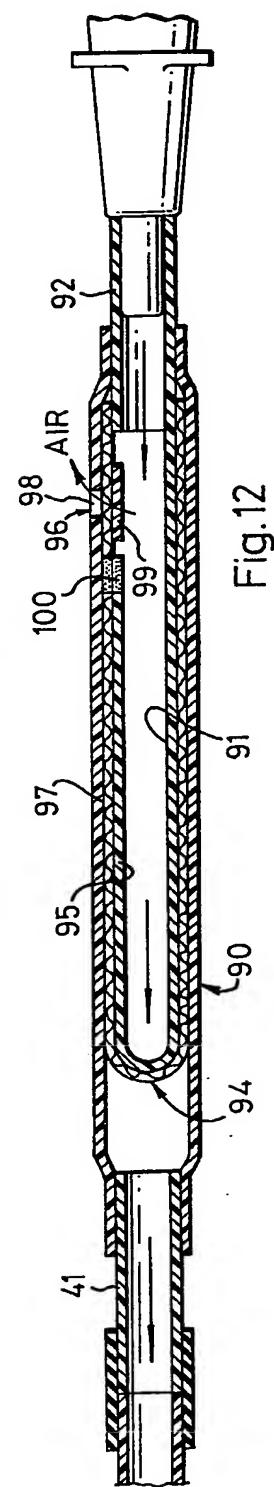
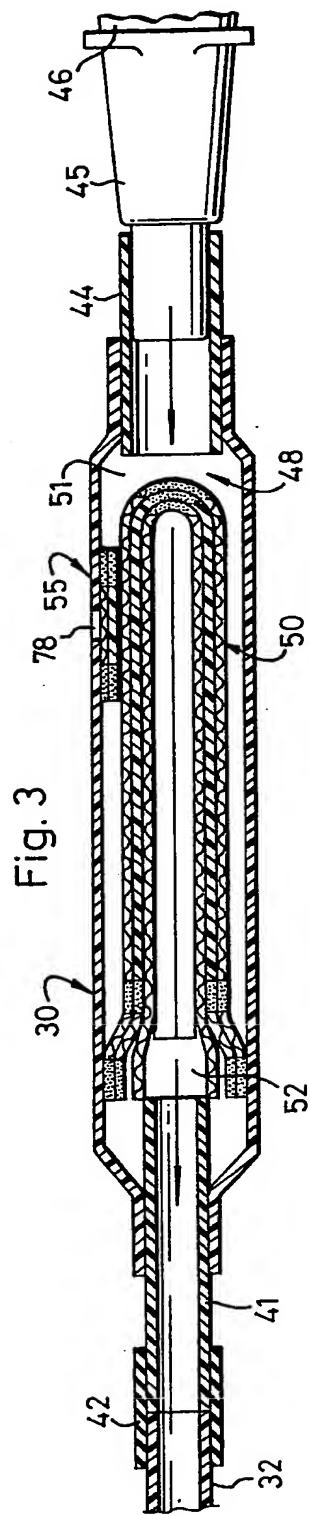
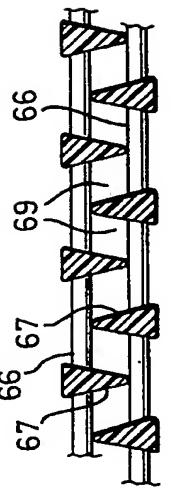
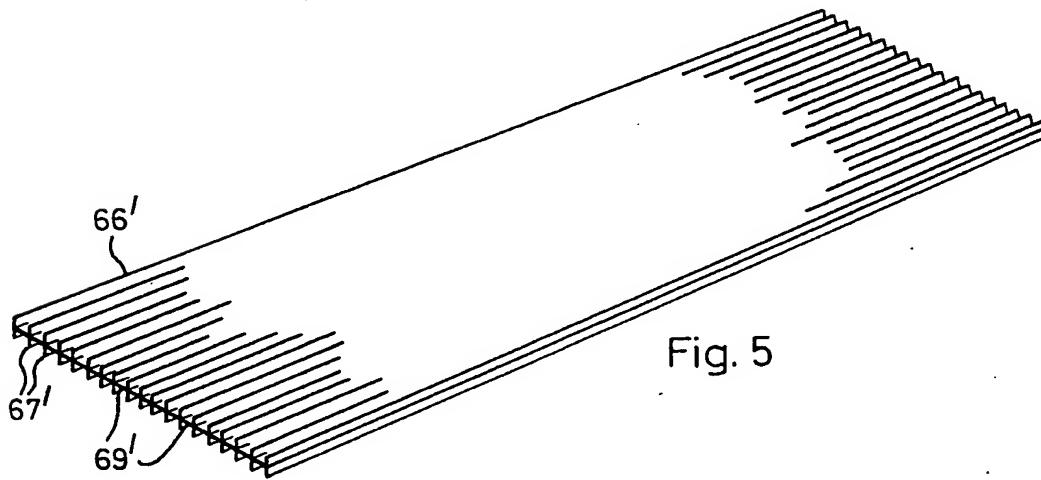
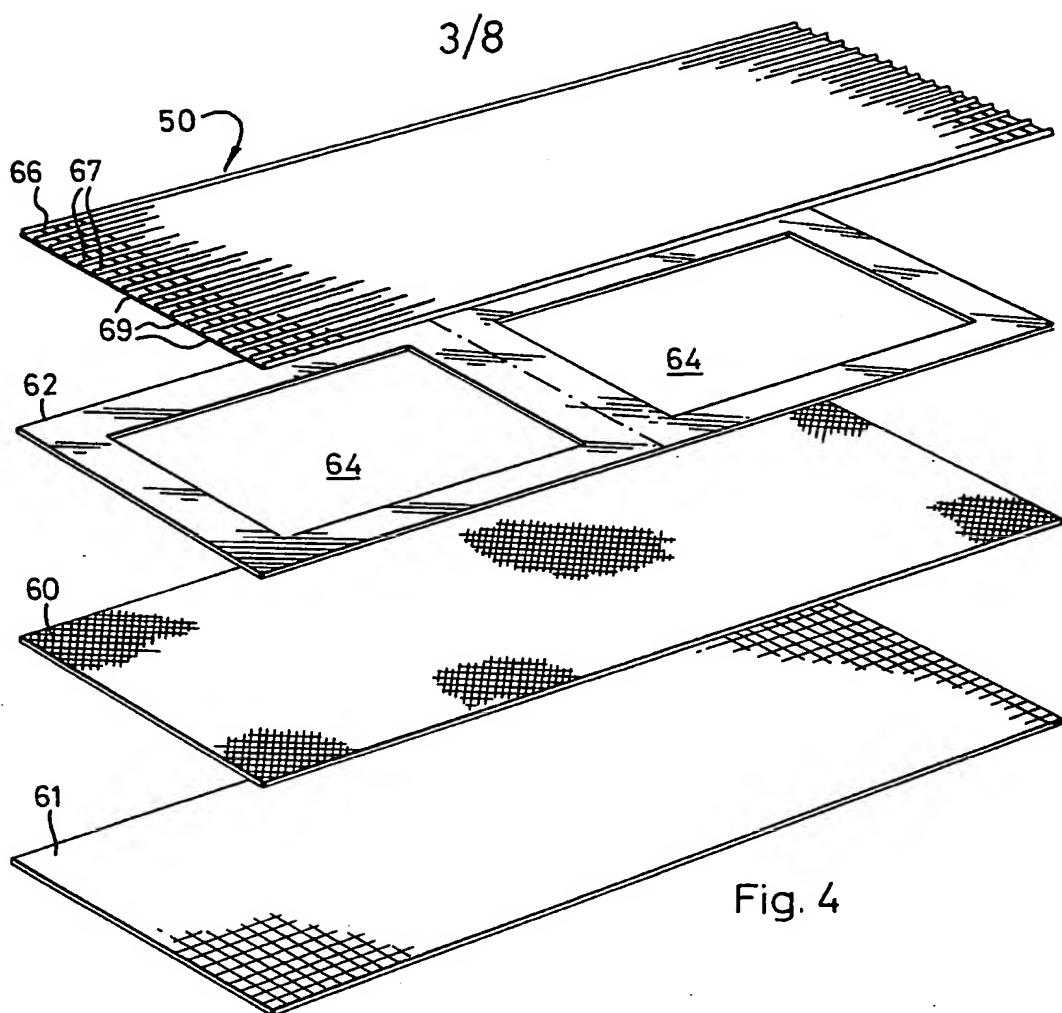


Fig. 7b

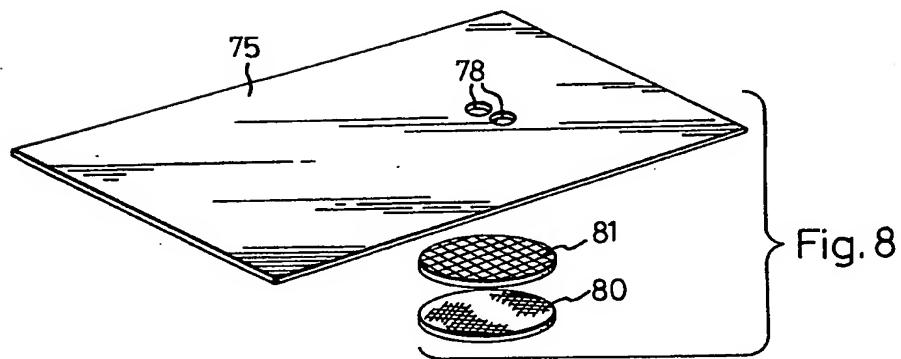
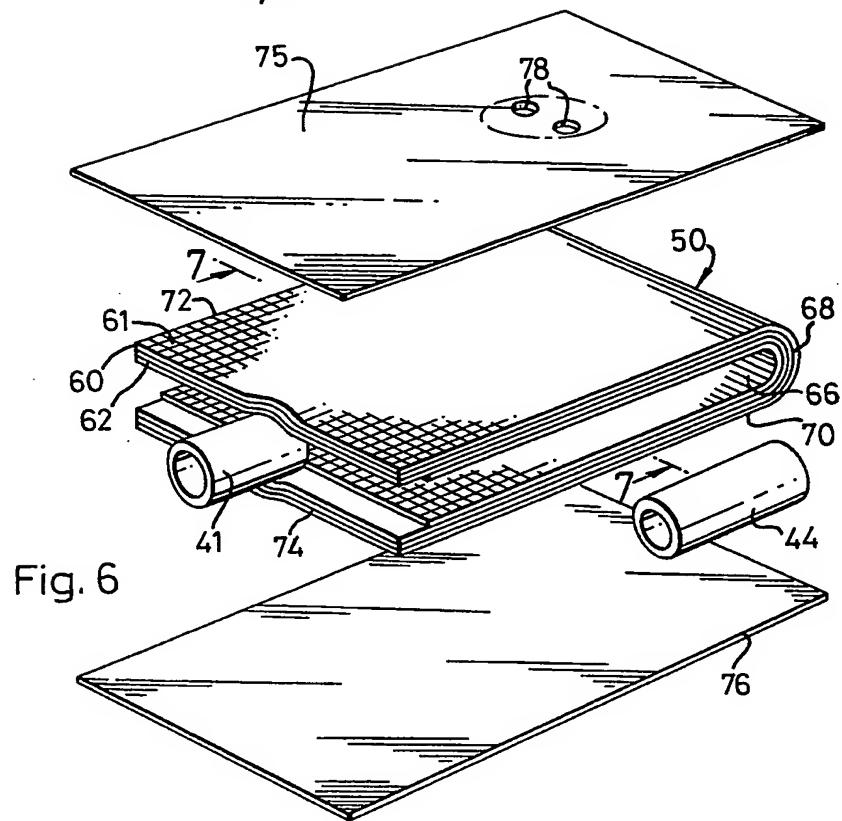


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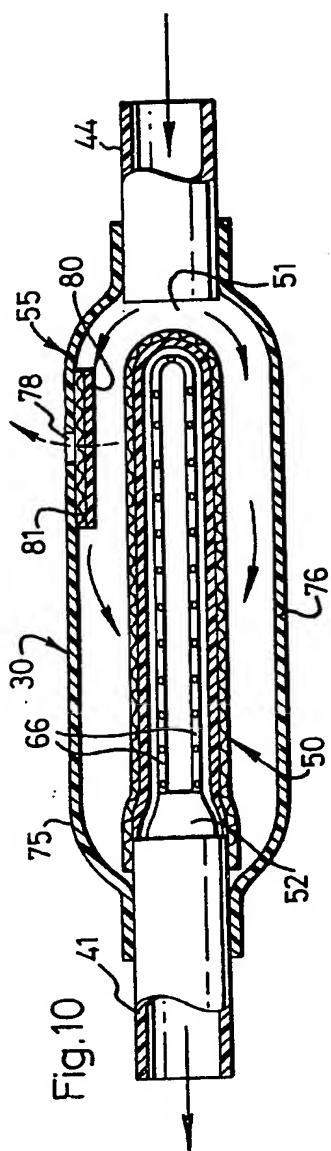
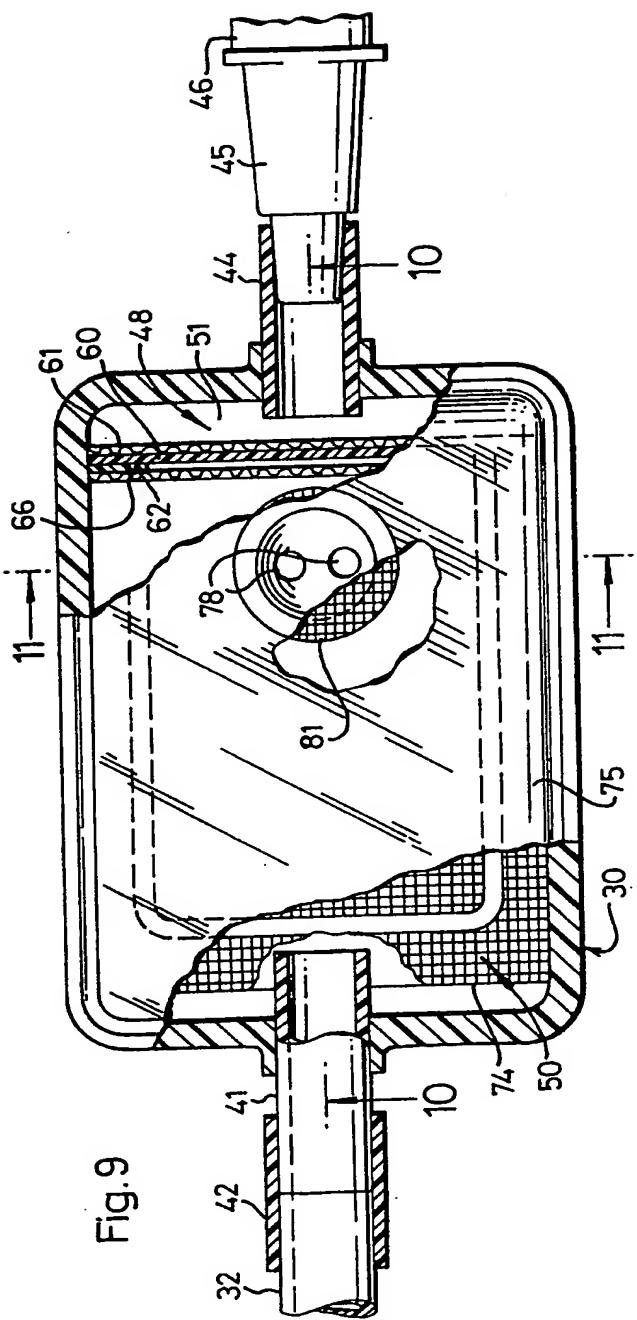
4/8

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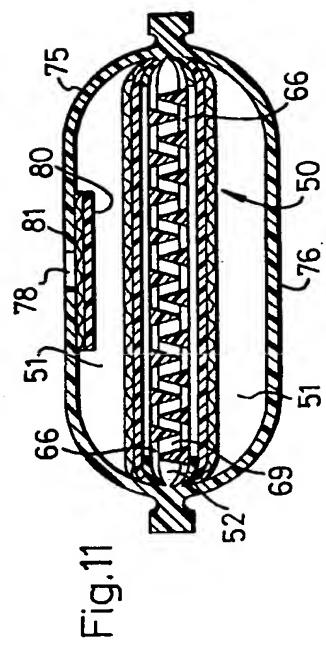


Fig.11

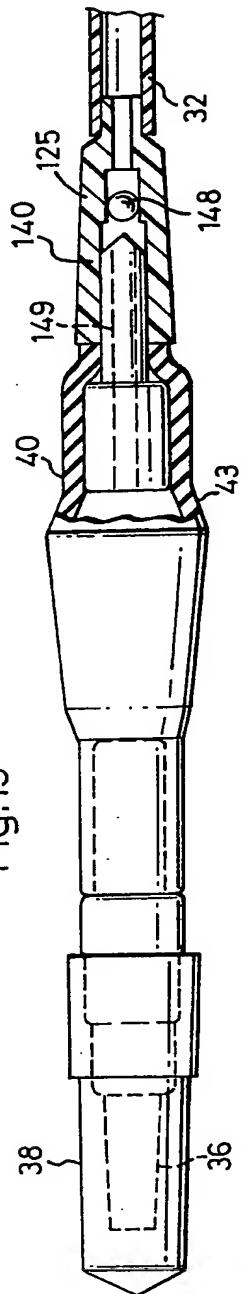


Fig.13

7/8

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Fig. 14

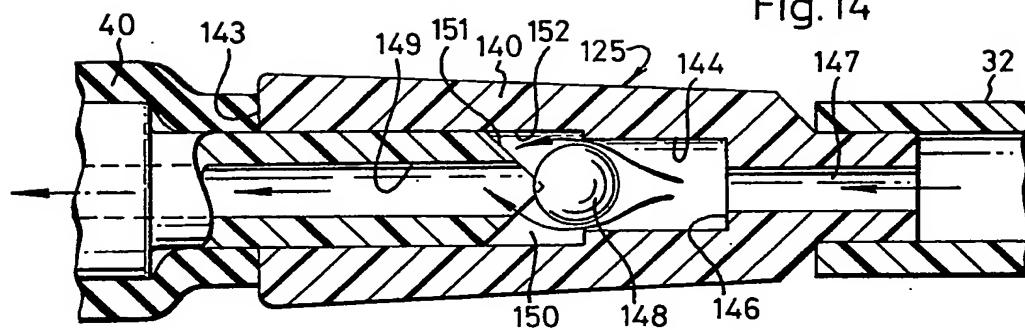


Fig. 15

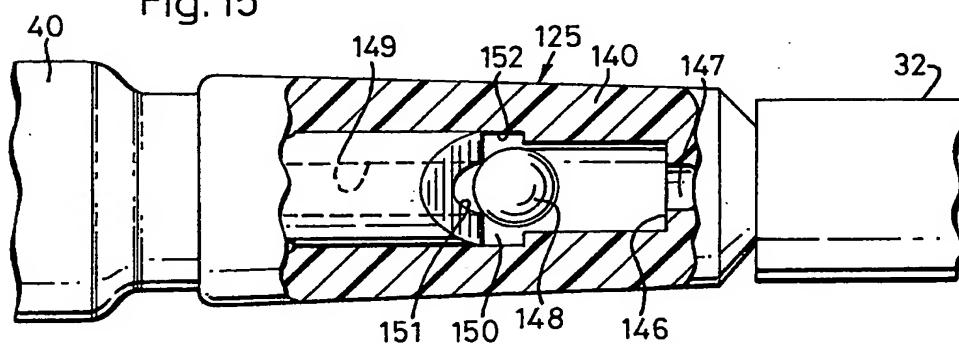


Fig. 16

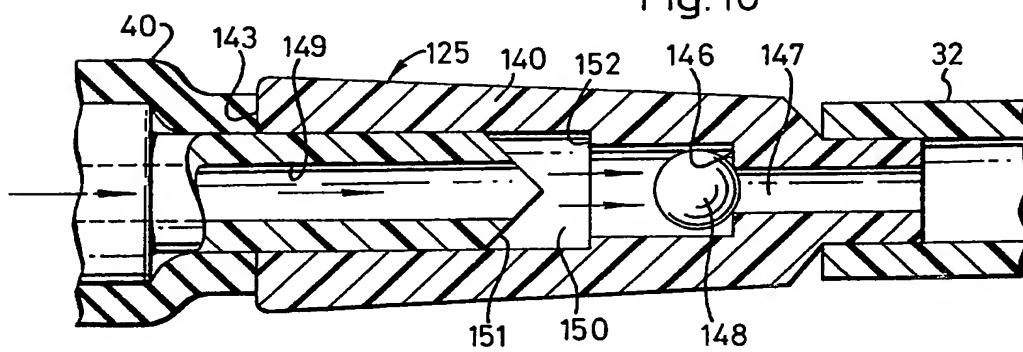


Fig. 17

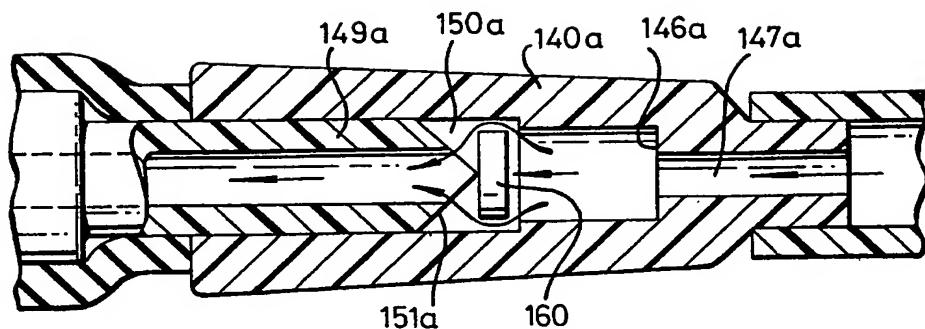
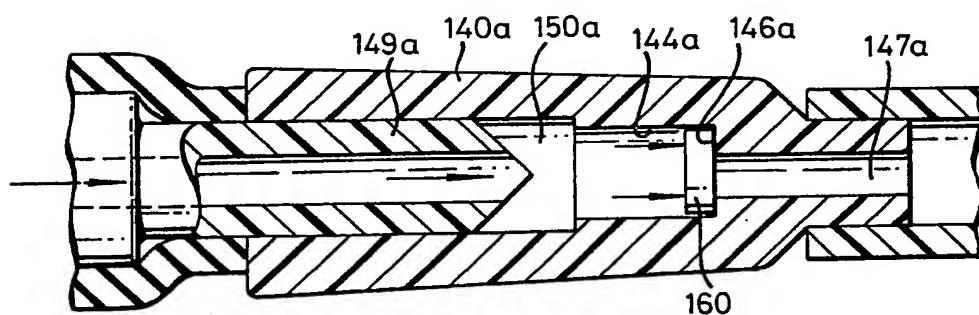


Fig. 18



## SPECIFICATION

### Vented filter assembly

5 The present invention relates to a fluid filter assembly and, more particularly, to unique vented filter assemblies which purge air therefrom in the filtering of parenteral and other fluids during the administration thereof. As  
10 used hereinafter and throughout this specification, reference to fluid and its filtration means the liquid state of the same rather than the gaseous state. Where air or other gases are discussed as being filtered or purged, they are  
15 specifically referred to as air or gas.

For some time it has been the preferred practice to filter intravenous and other parenteral solutions prior to the administration of such solutions to a patient to remove particulate matter that may be present in the solutions. Many different filter structures have been utilized for this purpose and many different procedures have been devised to insure that the fluids are properly filtered and administered with the highest degree of safety for the patient.

Recently, filter media have become commercially available that permit the filtration of intravenous fluids down to a particle size of 0.22 microns. This is significant in that a filter having this pore size effectively filters out all bacteria from the fluids in addition to removing particulate matter. Heretofore, one of the main drawbacks of utilizing a 0.22 micron filter was that a very high pressure drop was created by the presence of the filter, thus, necessitating the use of a pump to sufficiently overcome the back pressure. Also, the 0.22 micron membrane filter media that have been found to be particularly applicable for use in the filtering of intravenous fluids are exceptionally difficult to handle during the fabrication of the filter media into appropriate filter structures. This is true because most of such filter media have very low tear strengths and do not form adequate heat seals with other plastic materials. Therefore, the geometrical configurations heretofore available with the 0.22 micron membrane filter media have been relatively flat surfaces which greatly limit, because of size considerations, the available filter area for the passage of fluids. Thus, the problem of excessive back pressure is increased because of the relatively small filtering surfaces.

Another significant problem encountered in the use of prior filters was that of air blockage due to improper priming. Since the type of fluid filters contemplated by this invention have hydrophilic properties, they do not pass air and, consequently air accumulates at the filter surface and reduces the available filtration area. The result of this air accumulation at the filter surface is that it reduces the flow rate and contributes to the malfunction of the

system. A significant portion of this problem may be overcome by priming the filter assembly prior to its use; however, since prior filters have been constructed from relatively rigid housing materials, this priming technique has been relatively complicated and has not always been effective in removing all of the air from the filter housing.

One of the ways to prime the filter has been to separate the filter assembly itself from the intravenous tubing so that air can escape from the filter. This, of course, required the attendant to not only observe the intravenous flow for air blockage of the filter, but also to interrupt the intravenous feeding procedure to purge the air which is causing a blockage. As air enters the intravenous line due to a number of causes, it becomes necessary to constantly monitor the flow since the air does not purge itself, but requires some action on the part of the attendant or clinician.

A filter adapted to separate gases and liquids while performing the filtration function is disclosed in U.S. Patent No. 3 854 907. A non-wetting filter material allows gases inside the filter cover to be vented through a relatively long tubular cylinder and to be conducted to an outlet port in the bottom of the filter cover. This structure represents one way in which undesirable gas or air entering into a fluid filter assembly with fluid may be removed. U.S. Patent No. 3 149 758 discloses a liquid dispenser in which air entering therein is filtered by a hydrophobic filter material, and the ingress of microorganisms through a liquid outlet passage is prevented by a hydrophilic filter material. No means to purge undesirable air or other gases from this system is taught. Thus, there is room for further improvements in simplicity of structure, cost of manufacture, convenience of use and handling, and in performance and specific functions of a vented filter assembly.

### 110 SUMMARY OF THE INVENTION

A vented filter assembly comprises a closed housing having a fluid inlet and a fluid outlet. Included in the housing is an internal passage connecting the inlet and the outlet. A fluid filter is disposed within the passage between the inlet and the outlet thereby defining an upstream pressure section between the inlet and the filter and a downstream pressure section between the filter and the outlet. A gas vent located in the housing is adapted to allow gas but not fluid to pass from the upstream section of the passage out of the housing. All fluid passing from the inlet to the outlet passes through the fluid filter in use.

In the preferred embodiment the vented filter assembly is comprised of a flexible housing, and the fluid filter is a flexible pouch having a fluid opening in one end thereof with the outlet communicating with the interior of

the filter pouch through the filter opening. Disposed within the pouch is means to prevent the collapse of the flexible pouch on itself and thereby allow the flow of fluid therethrough when fluid passes from the passage through the pouch and into the interior thereof. In this embodiment, the gas vent includes at least one opening in the housing wall and a hydrophobic membrane filter medium attached to the housing wall to cover the opening thereby allowing undesirable air inadvertently entering the housing with fluid to pass out of the housing through the vent.

In the preferred embodiment of this invention, the fluid filter pouch is formed from a porous polycarbonate film, which has hydrophilic properties. This specific filter material provides certain advantages over other filter media usable with this invention in that it:

- 20 1) possesses superior heat-sealing properties;
- 2) does not swell in the presence of dextrose and other parenteral solutions (swelling of filter media can result in loss of flow rate over a period of time);
- 25 3) contains essentially no extractables, such as, surfactants, plasticizers, residual solvents, etc.; and
- 4) has very low moisture sensitivity.

From the structural standpoint, the vented filter assembly of the present invention is notably different from prior filter assemblies, for example, the filter holder disclosed in U.S. Patent No. 3 854 907. Specifically, the present vented filter assembly is more simple in construction and includes the gas vent directly in the housing wall rather than through an elongated passage as taught in the aforementioned patent. Furthermore, the flexible housing, the flexible fluid filter pouch and the means for preventing collapse of that pouch during fluid flow in the preferred embodiment of the present invention are features which individually and collectively contribute to the uniqueness of the present vented filter assembly. In accordance with the principles of this invention, the vented filter assembly overcomes the problem of air blockage of the fluid filter during administration of intravenous and other fluids. In the present vented filter assembly, gas, such as air in the intravenous fluid is purged, automatically, or on its own, without the need for any priming. This advantageous feature obviates the necessity for close monitoring of the intravenous system for air blockage, and moreover, eliminates the need, as in many previously known systems, to break and interrupt the intravenous flow to prime the filter and purge the air.

Another advantage of the present invention, particularly in the preferred embodiment hereof, is the ability to allow air to escape from the filter assembly irrespective of its orientation during fluid administrations; i.e., the vented filter assembly does not have to be

70 maintained in an upright or sideward position to take advantage of gravitational forces, since the construction of the preferred embodiment allows the escape of air and passage of fluid therethrough independent of gravitational orientation.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- 75
- Figure 1 is a perspective view illustrating a unique vented filter assembly of the present invention in place during the administration of intravenous fluids into a patient;
- 80 Figure 2 is a perspective view illustrating the entire filter assembly of one embodiment of the present invention;
- 85 Figure 3 is an enlarged cross-sectional view taken along lines 3—3 of Fig. 2;
- 90 Figure 4 is an exploded perspective view of the elements of one filter pouch of the present invention;
- 95 Figure 5 is a perspective view of an alternate fluid flow maintenance member for inclusion in the filter pouch;
- 100 Figure 6 is a perspective view illustrating the fabrication of the filter assembly;
- 105 Figure 7a is an enlarged cross-sectional view taken along lines 7—7 of Fig. 6 depicting the fluid flow maintenance member in one position when folded in the pouch;
- 110 Figure 7b is a cross-sectional view of the fluid flow maintenance member when folded illustrating the ridges shifted from the position illustrated in Fig. 7a;
- 115 Figure 8 is a perspective view illustrating the elements of one gas vent of the filter assembly;
- 120 Figure 9 is an enlarged plan view of one embodiment of the filter assembly with portions broken away to illustrate internal structure and fluid flow therethrough;
- 125 Figure 10 is a cross-sectional view taken along line 10—10 of Figure 9;
- 130 Figure 11 is a cross-sectional view taken along line 11—11 of Fig. 9;
- 135 Figure 12 is a cross-sectional view of another embodiment of the vented filter assembly of the present invention;
- 140 Figure 13 is an enlarged cross-sectional view taken along line 13—13 of Fig. 2;
- 145 Figure 14 is an enlarged cross-sectional view taken along line 14—14 of Fig. 2 illustrating the preferred backflow check valve during fluid flow through the device;
- 150 Figure 15 is a fragmented top view of the backflow check valve partially broken away to view the internal structure thereof;
- 155 Figure 16 is an enlarged cross-sectional view similar to the view of Fig. 14 illustrating the backflow check valve in the position to prevent fluid backflow therethrough;
- 160 Figure 17 is a cross-sectional view of the

catheter connector illustrating an alternate embodiment of the backflow check valve with fluid passing therethrough; and

Figure 18 is a cross-sectional view illustrating the embodiment of Fig. 17 in position to prevent fluid backflow.

#### DETAILED DESCRIPTION

- 10 While this invention is satisfied by embodiments in many different forms there is shown in the drawings and will herein be described in detail a preferred embodiment of the invention, with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to limit the invention to the embodiment illustrated. The scope of the invention will be pointed out in the appended claims.
- 15 Adverting to the drawings, particularly to Fig. 1, one embodiment of the vented filter assembly of the present invention is illustrated generally at numeral 15 attached to the arm A of a patient during the administration set
- 20 shown generally at 20. Administration set 20 comprises an intravenous solution container 22 which may be in the form of a glass bottle, plastic bag or other suitable means, and is preferably suspended approximately 2
- 25 to 3 feet (.71 to .92 m.) above the administration site. A length of tubing 24 having a spike 26 at the upper end thereof for penetrating the closure of intravenous solution container 22 extends downwardly from the container and delivers the intravenous fluid to filter assembly 15. A clamp 28 may be provided in tubing 24 to control the flow of fluid therethrough. Also, appropriate flow control devices, such as drip chambers or other fluid
- 30 control apparatus, may be associated with tubing 24, if desirable. This equipment is well known in the art of administering intravenous solutions and will not be described in further detail herein.
- 35 Referring to Fig. 2, vented filter assembly 15 is illustrated in greater detail and is shown to have a closed, flexible, compressible housing 30, a length of extension tubing 32 extending from one end of housing 30 and a
- 40 connector 34 attached to the other end of housing 30. Tubing 32 is adapted to be connected to a conventional intravenous catheter assembly and to deliver filtered intravenous fluid from the downstream (distal) end of
- 45 housing 30 to the intravenous catheter and, thus, into a vein of the patient. A suitable clamp 33 may be provided to control the flow of fluid through tubing 32. A connector 36 is attached to the end of tubing 32 and is
- 50 equipped with a male fitting that is adapted to be received into a female fitting on an intravenous catheter. A cap 38 is positioned over connector 36 to protect and preserve the sterility of the connector. Of course, cap 38
- 55 must be removed from connector 36 prior to

the attachment of the connector to the intravenous catheter. Connector 36 is attached in fluid communication to the end of tubing 32 by a fitting 40 which is preferably made of natural rubber, or a similar elastomer, which may be utilized as an injection site for medications or other fluids into the system. This injection is preferably accomplished by inserting the needle of a syringe or other device

60 into the tapered angular shoulder 43 provided on the fitting.

- In Fig. 3, the contents of the vented filter assembly are illustrated. A fluid outlet formed by a relatively short length of tubing 41 is provided in the downstream, distal end of housing 30 and tubing 32 is connected to tubing 41 by a sleeve 42 positioned over the mating ends of each of the pieces of tubing. A heat seal or other appropriate attachment
- 65 means may be utilized to facilitate bonding of these three elements together. The upstream, or proximal, end of housing 30 is also provided with a relatively short length of tubing 44 which provides a fluid inlet into housing
- 70 30 for the intravenous solution supplied by container 22. A female fitting 45 is secured in the proximal end of tubing 44 and is adapted to be connected to a male fitting on the distal end of tubing 24. A cap 46 is positioned in
- 75 the proximal end of fitting 45 to preserve sterility of the system and to protect the fitting. Of course, cap 46 must be removed from fitting 45 prior to the connection of tubing 24 thereto. Inside housing 30 is a
- 80 passage 48 connecting the inlet and outlet formed by the short tubing pieces. Disposed in passage 48 is a flexible fluid filter pouch 50 with a fluid opening in one end thereof. This fluid opening surrounds a portion of
- 85 outlet tubing 41 so that the outlet communicates with the interior of filter pouch 50 through the fluid opening therein. The disposition of pouch 50 thereby defines an upstream pressure section 51 in the passage between
- 90 inlet tubing 44 and filter pouch 50, and a downstream pressure section 52 in the passage between pouch 50 and the outlet tubing 41. In the filter assembly of the present
- 95 invention, some positive pressure is required across the filter pouch to force fluid through it; this positive pressure is on the upstream pressure section of the passage in the filter assembly. A gas vent 55 is located in one wall of housing 30 and communicates with
- 100 upstream section 51 of the passage. Gas vent 55 is adapted to allow gas but not fluid to pass from upstream section 51 of the passage out of housing 30, and will be discussed hereinafter in greater detail.
- 105 Turning to Fig. 4, the elements of the preferred fluid filter pouch of the present invention are illustrated in detail. A hydrophilic membrane filter sheet or film 60 is illustrated positioned adjacent a sheet of porous
- 110 reinforcing material 61. Because filter
- 115
- 120
- 125
- 130

sheet 60 generally possesses a relatively low burst strength in this application of the sheet, it has been found to be desirable to provide a reinforcing, or support, layer over substantially 5 the entire outer surface area of the film to prevent rupture, or other failure, of the film during use. Support layer 61 selected for this embodiment preferably is a polyvinylchloride scrim formed with preferably rectangular di- 10 mensions to support filter sheet 60. This support material has been found to provide effective support for hydrophilic filter sheet 60 without substantially affecting the flow rate of the fluid. Other support layer materials may 15 also be employed, such as non-apertured non-woven fabric composed of cellulosic wood pulp and polyester fibers bonded overall with a resin adhesive. This support material has been found to effectively support hydrophilic 20 filter sheet 60 without substantially affecting the flow rate when normal pressures are utilized during the administration of intravenous fluids.

It will be seen in Figure 4 that hydrophilic 25 filter sheet 60 and support sheet 61 have a frame member 62 disposed thereover. Frame 62 preferably has a central support member to add reinforcement when folded over. The use of frame 62 has been found to be beneficial in some instances when it is desirable to test the efficacy of the seal and burst strength 30 of filter sheet 60 prior to the incorporation of filter pouch 50 into a filter assembly, while it also contributes to the formation of the heat 35 seals during the fabrication of the filter assembly. It is noted that frame 62 has generally rectangular openings 64 to allow fluid to flow through hydrophilic filter sheet 60 in an unobstructed fashion. It has been found that a 40 frame of thin, thermoplastic material is most compatible for incorporation in pouch 50 of this invention.

Positioned above frame 62 is a fluid flow maintenance member 66. Maintenance member 45 66, in this instance, is a flat scrim material with a plurality of ridges 67 defining a plurality of channels 69 on one surface. Ridges 67 are spaced from each other so that 50 channels 69, running substantially parallel to each other along the long dimension of the flow maintenance member, are provided. In this embodiment, the ridged surface faces away from the filter sheet. The preferable material for the flow maintenance member is 55 a ridged polyvinylchloride scrim wherein the ridges are the longitudinally running filaments which form the scrim.

Another fluid flow maintenance member 66' is illustrated in Figure 5. In this embodiment 60 there are a plurality of ridges 67' on both surfaces of the maintenance member defining a plurality of channels 69' also on both surfaces. Maintenance member 66' is preferably formed from an elastomer such as 65 silicone rubber, and is non-porous, but flexi-

ble. It can be appreciated that the fluid flow maintenance member may take many different forms, and may even be a sheet of porous material; the purpose of the fluid flow maintenance member is to prevent the walls of the pouch from collapsing on each other, thereby preventing fluid flow, while allowing fluid to flow into, then out of, the pouch.

While many embodiments of the fluid filter 70 pouch of this invention may be fabricated without support sheets or frame members, the filter media contemplated for use with the present invention are membrane-type materials that have the capability of filtering particles and bacteria having a size down to 0.22 microns. The presently available commercial material usable in this type of application is extremely difficult to handle and to fabricate. For example, it has been found that most 75 available membrane filter media of this type have a common problem with regard to sealing, that is, the filter media do not lend themselves to conventional sealing techniques, such as heat sealing, solvent sealing, ultrasonic sealing, etc. To overcome these 80 drawbacks, one aspect of the present invention is to provide a unique procedure for supporting this type membrane filter media and for fabricating it in a pouch configuration. 85 For example, it has been found that most available membrane filter media of this type have a common problem with regard to sealing, that is, the filter media do not lend themselves to conventional sealing techniques, such as heat sealing, solvent sealing, ultrasonic sealing, etc. To overcome these 90 drawbacks, one aspect of the present invention is to provide a unique procedure for supporting this type membrane filter media and for fabricating it in a pouch configuration. 95 For example, it has been found that most available membrane filter media of this type have a common problem with regard to sealing, that is, the filter media do not lend themselves to conventional sealing techniques, such as heat sealing, solvent sealing, ultrasonic sealing, etc. To overcome these 100 drawbacks, one aspect of the present invention is to provide a unique procedure for supporting this type membrane filter media and for fabricating it in a pouch configuration. 105 For example, it has been found that most available membrane filter media of this type have a common problem with regard to sealing, that is, the filter media do not lend themselves to conventional sealing techniques, such as heat sealing, solvent sealing, ultrasonic sealing, etc. To overcome these 110 drawbacks, one aspect of the present invention is to provide a unique procedure for supporting this type membrane filter media and for fabricating it in a pouch configuration. 115 For example, it has been found that most available membrane filter media of this type have a common problem with regard to sealing, that is, the filter media do not lend themselves to conventional sealing techniques, such as heat sealing, solvent sealing, ultrasonic sealing, etc. To overcome these

When the elements of pouch 50 are folded over, the interior element is flow maintenance member 66. Thus, the folded portions of maintenance member 66 are disposed adjacent each other in overlying relationship. In Figure 7a, it can be seen that ridges 67 abut each other in point to point contact after maintenance member 66 has been folded over. This point to point contact of ridges 67 provides maximum openings for channels 69 through which fluid flows through the filter pouch. The purpose of these ridges is to maintain the channel passages so that the pressure of the fluid passing into the pouch does not collapse the folded portions of the

maintenance member 66 against each other and thereby block fluid flow through the pouch. Inasmuch, however, as maintenance member 66 is a flexible, porous scrim, ridges 67 do not always remain aligned in the fold in point to point contact: they tend to slip to one side. For instance, Fig. 7b illustrates ridges 67 of opposite overlying portions of maintenance member 66 in alternating disposition, 10 in saw-tooth fashion. Rather than point to point contact, each ridge 67 abuts against the opposite surface of maintenance member 66; this, of course, prevents the overlying surfaces from being forced against each other and 15 prevent fluid from passing through channels 69. Accordingly, as channels 69 are maintained between ridges 67, fluid is allowed to flow into the pouch, through the pores in maintenance member 66, and travel along 20 channels 69 to the fluid outlet.

To complete the filter assembly, filter pouch 50 is enclosed with a flexible, compressible housing formed by two flexible plastic sheets 75 and 76. Plastic sheets 75 and 76 are 25 preferably heat sealed to filter pouch 50 along adjacent edges 70 and 72. Concurrently with this heat sealing operation, tubing 41 is sealed between the folded over portions of the pouch along edge 74; edge 74 is also sealed 30 so that tubing 41 provides the only opening or access to the interior of pouch 50. Inlet tubing 44 is concurrently sealed between plastic sheets 75 and 76 to provide the fluid inlet for the filter assembly. In plastic sheet 35 75, which forms one wall of the completed filter housing, there are two small openings 78 provided therethrough, the openings being part of the gas vent feature of the present invention. A preferable construction of the gas 40 vent is illustrated in Fig. 8.

Although plastic sheet 75 includes, in this instance, two small openings 78, the number of openings to allow air or other gases to escape from the housing is not critical and 45 may vary in size and amount depending on many factors including anticipated volume of gas to purge and fabrication requirements. On the surface of plastic sheet 75 which will face the interior of the housing, openings 78 are 50 covered by a membrane filter medium 80 with hydrophobic properties. Hydrophobic filter 80 is preferably disc shaped and is sufficient in size to cover openings 78 in plastic sheet 75. To facilitate the attachment 55 of hydrophobic filter 80 to plastic sheet 75, and to employ heat sealing techniques as the preferable operation of assembly, a support disc 81, porous in nature, is positioned between plastic sheet 75 and hydrophobic filter 60 80 in the heat sealing step. Support disc 81 is desirably a plastic scrim material which not only provides good heat sealing characteristics but does not affect the flow rate of gas which escapes through hydrophobic filter 80 and 65 passes out of the housing through openings

78. Thus, in the completed filter assembly, the gas vent, including hydrophobic filter 81, is attached directly to the interior wall of the housing so that gas or air in the housing may be purged directly out of the housing in the most expedient manner.

The completed structure of this embodiment of the vented filter assembly of the present invention is illustrated in Fig. 9. Pouch 50 is shown disposed within passage 48 inside housing 30, with outlet tubing 41 communicating with the interior of pouch 50 through the fluid opening in edge 74. The pouch components and the flexible plastic sheets 80 which form the housing for the filter assembly are sealed along their edges to produce a closed filter assembly except for the fluid inlet and outlet formed by tubings 44 and 41 respectively, and gas vent openings 78. In 85 use, fluid from the administration set enters housing 30 of the vented filter assembly through inlet tubing 44. This fluid is, of course, contemplated to be in the liquid state so that it may be fed into the vein of the 90 patient. As sometimes occurs, gas, such as air, is in the line travelling from the intravenous solution container, and that undesirable air also enters housing 30 of the filter assembly with the fluid. Figs. 10 and 11 graphically 95 illustrate the filter assembly of this invention in use and during the passage of fluid therethrough.

Fluid enters the housing through inlet tubing 44 and travels into upstream pressure 100 section 51 of the passage inside housing 30. As fluid enters, pockets or bubbles of air may be mixed with the fluid. Inasmuch as the fluid in upstream pressure section 51 is under positive pressure, the fluid is forced through 105 filter pouch 50, including the hydrophilic filter membrane therein, into downstream pressure section 52 with which outlet tubing 41 communicates. Thus, all fluid passing from inlet 44 to outlet 41 passes through filter pouch 110 50 thereby filtering out particulate matter, including bacteria, so that the fluid passing out of filter housing 30 has a higher degree of safety before entering the patient.

Inasmuch as the hydrophilic membrane 115 filter in pouch 50 generally has very small openings for filtration purposes, air in the fluid would have a tendency to accumulate on the openings to cause a blockage of fluid flow through the filter pouch. This problem is obviated by inclusion of gas vent 55 in housing 30. By locating gas vent 55 to communicate with upstream pressure section 51, the positive pressure in that section of the passage tends to force air or other gases in the fluid 120 out of openings 78 in plastic sheet 75 of housing 30. The hydrophobic nature of gas vent filter 80 permits air to escape from passage 51, but its non-wetting characteristics 125 prevent any of the fluid from escaping from 130 gas vent 55. Thus, undesirable air in the

- intravenous fluid entering the filter assembly of this invention is purged from the system automatically, thereby eliminating the possibility of air blockage at the fluid filter and
- 5 assuring unimpeded flow of the fluid through the fluid filter. It is noted in referring to Figs. 10 and 11 that flexible plastic sheets 75 and 76 defining flexible housing 30 tend to bulge out and separate away from filter pouch 50
- 10 within housing 30 so that sufficient volume of fluid may pass through the filter assembly.

As oftentimes occurs when employing a filter assembly in the administration of intravenous fluids, the orientation of the filter assembly is unpredictable, with the filter assembly lying in any position depending upon where and how it is included in the administration hookup. Accordingly, in using the gas vent feature of the present invention, air must be allowed to escape irrespective of the position of the filter assembly during fluid administration. To accomplish this, it has been found preferable to orient filter pouch 50 inside filter housing 30 so that the fluid opening in pouch 50 is connected to outlet tubing 41, rather than to inlet tubing 44. The effect of this construction, plus the fact that positive fluid pressure is in upstream pressure section 51 inside housing 30, would normally cause flexible filter pouch 50 to collapse on itself thereby impeding or possibly completely blocking fluid flow through the filter assembly. To overcome the collapse of filter pouch 50, fluid flow maintenance member 66 is disposed

25 within filter pouch 50.

In Fig. 11, it can be seen that fluid flow maintenance member 66 prevents the walls of fluid pouch 50 from completely collapsing on themselves to prevent fluid from through the filter assembly. The force of the fluid from upstream pressure section 51 forces each wall of filter pouch 50 inwardly towards each other. However, the fluid force urges each maintenance member toward each other so that the points of ridges 67 on each folded portion prevent complete surface to surface contact of the maintenance member. Accordingly, channels 69 are maintained between ridges 67. Fluid passing through filter pouch 50 passes through the pores of ridged maintenance member 66 to channels 69 which carry the flowing fluid through filter pouch 50 in downstream pressure section 52 to outlet tubing 41. Thus, fluid flow is assured through

55 the filter assembly having a construction wherein air is automatically purged therefrom irrespective of its position during fluid administration. Other configurations of fluid flow maintenance member 66 are readily conceivable to provide a channel inside filter pouch 50 to carry the flowing fluid to outlet tubing 41, the fluid flow maintenance member illustrated in the drawings herein merely being a preferable embodiment.

65 There are instances in which the position of

- the fluid filter assembly has a fixed orientation during the administration of fluids to a patient. In those instances, it is not always necessary to provide a vented filter assembly with a fluid flow maintenance member or the equivalent. For example, an alternate fluid filter assembly is illustrated in Fig. 12 which includes a gas vent feature, but no fluid flow maintenance member.
- 70 The embodiment of Fig. 12 is similar in many respects to the embodiment previously discussed. In the housing 90 of this filter assembly, the filter pouch 91, while constructed according to the same principles as discussed above, is positioned in housing 90 so that its fluid opening is attached to inlet tubing 92, whereby the inlet communicates with the interior of pouch 91. Outlet 94 receives flowing fluid from the interior of housing 90 after passing through filter pouch 91. Filter pouch 91 embodies hydrophilic filter 95 through which the flowing fluid is filtered. A gas vent 96 is included in upper plastic sheet 97 and includes at least one opening 98 therein and a hydrophobic filter membrane 99 attached to the interior surface of plastic sheet 97 to cover opening 98. A support sheet may be interposed between hydrophobic filter 99 and plastic sheet 97 to assure proper sealability. To maintain gas vent 96 in the upstream pressure section of the passage inside housing 90, pouch 91 is sealed to plastic sheet 97 along seal line 100. Thus, when air inadvertently enters through
- 100 inlet tubing 92, it is purged directly out of the housing through opening 98 rather than passing into the area inside pouch 91. This, of course, prevents air blockage of the openings of the filter pouch through which fluid flows.
- 105 This filter assembly is desirably oriented in the administration hookup so that the vent opening is near the top of the assembly, whereby air which rises will be automatically purged out of the housing rather than accumulating
- 110 on the surface of the hydrophilic filter inside pouch 91.
- Figs. 13-16 illustrate a backflow check valve incorporated in the extension set line. The purpose of this fluid backflow check valve is to allow one-way flow of fluid into the patient, but to prevent backflow of blood or other fluids into the intravenous extension line, and especially from backflowing into the filter assembly. If blood backflows into the
- 115 filter, the pores of the filter medium may become plugged thereby rendering the filter inoperative.
- Fluid backflow check device 125 is disposed between extension tubing 32 and fitting 40, and is adapted to be connected to each in fluid tight arrangement. The components of backflow check device 125 are more clearly illustrated in Figs. 14-16, which also depict the operation of the check device especially in performing the backflow prevention
- 120
- 130

features of the present invention.

Backflow check device 125 includes a housing 140 which, in this instance, includes a bore 144 extending therethrough thereby defining a large opening 143 at one end and a smaller opening 147 at the other end. Shoulder 152 is included for structural support, while shoulder 146 acts as a valve seat as hereinafter discussed. Small opening 147 serves as a fluid inlet to the housing. A ball 148, inside the housing, serves as a valve which cooperates with valve seat 146 to close off the flow of liquid backflowing into the housing.

15 Inserted in large opening 143 is a relatively rigid, hollow length of tubing 149. Tubing 149 extends into the bore of the housing, but leaves a space between its end and valve seat 146 to define an internal passage or cavity 150 within the housing. At the other end, tubing 149 projects out of housing 140 and is adapted to be inserted in the passage of fitting 40 of the catheter. Tubing 149 serves as a fluid outlet through which fluid flows out 25 of housing 140 and thereby into the catheter. The end 151 of tubing 149 inside the housing has been tapered in arrow head fashion so that ball 148, when urged thereagainst during fluid flow through the housing, does not completely seal the opening of tubing 149 thereby allowing fluid to flow into the outlet without a stoppage.

Internal cavity 150 is a passage within the housing connecting the fluid inlet and the fluid outlet, both of which communicate with the cavity. The cavity and the ball therein have a size relationship so that the ball has freedom of movement in the cavity to move towards and away from the inlet, particularly 35 valve seat 146. In addition, the outlet and inlet openings, tubing 149 and small opening 147, respectively, have cross-sectional dimensions smaller than the diameter of ball 148 to thereby prevent the ball from escaping the internal cavity. Ball 148 is preferably made from a heavy material such as stainless steel or any other metal or material which will provide it with a specific gravity greater than the fluid flowing through the housing of the 45 back check device. In this regard, the ball will not float in the fluid passing through the back check device, but is urged by the force and pressure of the fluid flowing therethrough.

In use, fluid in extension tubing 32 is 55 connected to housing 140, provides a forward pressure so that fluid flows towards the patient's vein as seen especially in Fig. 14. Before reaching the patient, fluid flows through inlet opening 147 into internal cavity 60 150 of the backflow check device. Fluid entering the internal cavity urges ball 148 away from valve seat surface 146 of the inlet opening. The force of fluid pressure directs ball 148 against end 151 of outlet tubing 65 149. However, the opening of outlet tubing

149 is not completely blocked, thereby allowing fluid to escape therethrough. Thus, during normal fluid flow, continuous passage of the fluid toward the patient is not interrupted by 70 the fluid backflow check device of the present invention.

Referring to Fig. 15, it can be seen that the arrow head end 151 is angled so as to stop ball 148 from completely plugging up the opening. Fluid flows around the ball and the upstream pressure forces the fluid into the outlet of hollow tubing 149.

On the other hand, there are instances when the venous pressure of blood from the 80 patient is greater than the forward pressure of the fluid in the feedline tubing. When this situation arises, a backflow of fluid and blood occurs. This backflow is basically a flow of blood or fluid in the reverse direction, back 85 into the feedline towards the filter device. If blood is allowed to enter the filter device through its outlet opening, the blood may plug up the pores of the filter medium within, thereby stopping flow of the intravenous fluid 90 even when the pressures have corrected themselves. To prevent this undesirable fluid or blood backflow, as illustrated in Fig. 16, the fluid backflow check device of the present invention is provided. It can be seen in that 95 drawing that fluid backflowing through outlet tubing 149 into internal cavity 150 urges ball 148 towards valve seat 146. The force of the backflowing fluid causes ball 148 to mate with valve seat surface 146, and together 100 they cooperate to provide a fluid seal. This prevents fluid from passing out of the housing through the inlet opening 147. Thus, no blood from the patient's vein will be permitted to backflow through the feedline towards the 105 filter device.

In addition, the mating of ball 148 and valve seat 146 cooperate to prevent air from entering extension tubing 32 of the administration set. This, of course, prevents deprimenting of the filter device once it has been primed.

Referring to Fig. 17, an alternate embodiment of the valve means is illustrated. Housing 140 is similar to housing 140 in the previously discussed embodiment and has an internal passage or cavity 150a within. Hollow tubing 149a defines a fluid outlet whereas small opening 147a defines a fluid inlet to housing 140a. Instead of a ball as in the previous embodiment, the movable valve means is a substantially flat disc 160. Disc 160 is light-weight and is preferably made of flexible material so as to lend more resiliency in its movement to open and close the housing to fluid flow. As seen in Fig. 17, fluid flows into the housing through small opening 147a and urges disc 160 away from valve seat surface 146a towards the arrow head point 151a of tubing 149a. Disc 160 does 120 not block the opening in tubing 149a inas-

much as fluid may pass around the disc and into the opening due to the upstream pressure of the fluid. Thus, fluid travelling one-way from a fluid container upstream of this device, 5 and towards the patient, downstream of this device, readily passes through the housing of this backflow check device in a continuous, unobstructed fashion.

Disc 160, being light-weight in character 10 and conforming closely to the diameter of bore 144a of the housing, responds readily to the urging force of fluid passing through the housing. In Fig. 18, the position of disc 160 in housing 140a is illustrated when fluid 15 backflows from the patient into the housing. As fluid enters internal cavity 150a, it urges disc 160 away from tubing 149a and towards valve seat 146a. The force of the fluid maintains disc 160 in sealing arrangement with 20 valve seat 146a to effectively block the flow of fluid into small opening 147a. Thus, the cooperation of the disc and the valve seat prevents fluid from backflowing out of the housing through the inlet opening 147a.

25 Once positive pressure of the fluid is restored in the extension tubing, fluid again flows towards the patient, with disc 160 moving in the appropriate direction to allow fluid flow through the housing.

30 The preferred embodiment of the present invention contemplates the use of a unique hydrophilic membrane filter material which has certain properties that are superior to the properties of other filter media usable with the 35 invention. This unique hydrophilic membrane filter material is a polycarbonate film which is available from the Nuclepore Corporation and is made in accordance with that company's unique manufacturing process. The material is 40 marketed under the trade name "NUCLE-PORE". The polycarbonate membrane is unique as a filter media for the subject invention because of its following properties:

1. the polycarbonate membrane possesses 45 heat-sealing properties which are superior to the properties of other membrane filter media which are commercially available and adaptable for use with the present invention. This, of course, enables the membrane to be handled 50 in a manner different from that of other filter media;
2. the polycarbonate film has been found to be extremely stable and does not swell in the presence of dextrose and other sugar 55 containing parenteral solutions. This is an advantage in that swelling of the filter media in the presence of these solutions can result in loss of flow over a period of time;
3. the polycarbonate film contains essentially no undesirable extractables, such as surfactants, plasticizers, residual solvents, etc.; and 60
4. the unique membrane has very low moisture sensitivity.

65 The polycarbonate membranes are manufac-

tured in accordance with a unique two-step manufacturing process. In accordance with this process, a polycarbonate film is first exposed to collimated, charged particles in a nuclear reactor. As the particles pass through the material, they leave sensitized tracks. The pore density (pores/cm<sup>2</sup>) is controlled by the residence time in the irradiator. In the second step of the manufacturing process, the tracks left by the charged particles in the reactor are preferentially etched into uniform, cylindrical pores. By controlling the length of the etching process, a specified pore size is produced. In its preferred condition, the pore size of this polycarbonate film is about 0.2 microns, and the thickness of the film is about 10 microns. Other membrane filter media are usable with the present invention, such as membranes formed from mixed esters of cellulose 85 reinforced with a polyester mesh.

While various filter membranes may be used as the hydrophobic filter, it has been found preferable to use polyvinylchloride laminated porous polytetrafluoroethylene film as 90 this filter material. In most applications, the pore size of this hydrophobic filter is about 0.2 microns, while the thickness of the membrane is about 50 microns. Generally, the size of the hydrophobic filter is much smaller than 95 the hydrophilic filter since the volume of air to be purged is not great; however, size of the hydrophobic filter is not critical, and can be selected generally according to choice, practicability and fabrication convenience.

100 Although all of the materials utilized in the construction of the filter assembly of the present invention are not critical, it will be appreciated that the materials should preferably be bio-compatible and that, in order to facilitate 105 fabrication of the filter assembly, most of the materials should desirably be heat-sealable. By way of example, the outer plastic sheets of the flexible housing are preferably formed from polyvinylchloride having a thickness of 8 mils (0.02 cm.). Likewise, all of the tubing, 110 including tubing 32, 41 and 44, are preferably constructed of polyvinylchloride. The size of the filter pouch and the housing are also not critical; however, it has been found that 115 the overall dimensions should be limited in order to conveniently position the filter assembly on the arm of a patient but at the same time provide the superior flow rates achievable with this unique filter structure. The presently preferred outside dimensions for the filter housing are 2 inches (5.08 cm.) from the distal to the proximal end, and 1 1/4 inches (3.18 cm.) wide.

120 Thus, it is apparent that there has been provided in accordance with the invention a vented fluid filter assembly that fully satisfies the aims, advantages and aspects as set forth above.

**CLAIMS**

1. A vented filter assembly comprising: a closed housing having a fluid inlet and a fluid outlet, said housing including an internal passage connecting said inlet and outlet; a fluid filter disposed within said passage between said inlet and outlet thereby defining an upstream pressure section between said inlet and said filter and a downstream pressure section between said filter and said outlet, all fluid passing from said inlet to said outlet passing through said fluid filter in use; and a gas vent in said housing adapted to allow gas but not fluid to pass from said upstream section of said passage out of said housing.
2. A vented filter assembly as defined in Claim 1 wherein said fluid filter is a hydrophilic membrane filter medium.
3. A vented filter assembly as defined in Claim 2 wherein said fluid filter is a flexible pouch having a fluid opening in one end thereof.
4. A vented filter assembly as defined in Claim 3 wherein said filter pouch is formed from a single sheet of membrane filter medium folded substantially in half and having seal means along two edges adjacent the folded edge.
5. A vented filter assembly as defined in Claim 4 further comprising means to support said filter pouch in said housing.
6. A vented filter assembly as defined in Claim 5 wherein said support means is a porous sheet of material overlying substantially the entire outer surface area of said membrane filter medium, said support sheet being folded substantially in half to conform to said folded filter medium.
7. A vented filter assembly as defined in Claim 3 wherein said inlet opening communicates with the interior of said filter pouch through said fluid opening.
8. A vented filter assembly as defined in Claim 2 wherein said fluid filter is a porous polycarbonate film.
9. A vented filter assembly as defined in Claim 8 wherein the pore size of said film is about 0.2 microns.
10. A vented filter assembly as defined in Claim 1 wherein said housing is flexible and compressible.
11. A vented filter assembly as defined in Claim 10 wherein said housing is comprised of a pair of flexible sheets sealed together around their peripheries.
12. A vented filter assembly as defined in Claim 1 wherein said gas vent includes an opening through said housing and a hydrophobic membrane filter medium attached to said housing to cover said opening, thereby allowing only gas to escape therethrough.
13. A vented filter assembly as defined in Claim 12 wherein said hydrophobic membrane is a porous film of polyvinylchloride laminated tetrafluoroethylene film.

14. A vented filter assembly as defined in Claim 13 wherein the pore size of said film is about 0.2 microns.
15. A vented filter assembly comprising: a closed housing comprising a pair of flexible sheets sealed together around their peripheries except for a fluid inlet and a fluid outlet, said housing having an internal passage connecting said inlet and outlet; a flexible fluid filter pouch having a fluid opening in one end thereof disposed within said passage with said inlet communicating with the interior of said filter pouch through said fluid opening, thereby defining an upstream pressure section in the passage between said inlet and said filter pouch and a downstream pressure section in said passage between said filter pouch and said outlet, said filter pouch comprising a hydrophilic membrane filter medium folded substantially in half and having seal means along two edges adjacent the folded edge and a porous support sheet overlying substantially the entire outer surface of said hydrophilic filter medium, said sheet being folded substantially in half to conform to said folded filter medium; and a gas vent comprising at least one opening through one of said flexible sheets of said housing communicating with said upstream section of said passage and a hydrophobic membrane filter medium attached to the interior surface of said flexible sheet to cover said opening, whereby in use air entering said housing with fluid passes out of said housing through said vent to thereby prevent air blockage of said fluid filter pouch through which fluid passes before exiting out of said housing through said outlet.
16. A vented filter assembly as defined in Claim 15 wherein said hydrophilic filter is a porous polycarbonate film, and said hydrophobic filter is a polyvinylchloride laminated tetrafluoroethylene film, both films having a pore size of about 0.2 microns.
17. A vented filter assembly as defined in Claim 15 wherein said pouch includes a frame member overlying the surface of said filter medium opposite said supported surface, said frame member having at least one central opening exposing a substantial surface area of said filter sheet, and said frame member also being folded substantially in half in said folded pouch.
18. A vented filter assembly comprising: a closed housing having a fluid inlet and a fluid outlet, said housing including an internal passage connecting said inlet and outlet; a flexible fluid filter pouch disposed in said passage between said inlet and said outlet thereby defining an upstream pressure section in the passage between said inlet and said pouch and a downstream pressure section between said pouch and said outlet, said pouch formed from a membrane filter medium and having a fluid opening in one end thereof, said outlet communicating with the interior of said filter

- pouch through said fluid opening; a fluid flow maintenance member disposed within said pouch for preventing the collapse of said pouch on itself during fluid flow from said pouch through said upstream section through said pouch filter membrane to said downstream section; and a gas vent in said housing adapted to allow gas but not fluid to pass from said upstream section of said passage out of said housing.
- 10 19. A vented filter assembly as defined in Claim 18 wherein said housing is flexible and compressible.
20. A vented filter assembly as defined in Claim 19 wherein said housing is comprised of a pair of flexible sheets sealed together around their peripheries.
21. A vented filter assembly as defined in Claim 18 wherein said maintenance member is a scrim having a plurality of ridges defining a plurality of channels on one surface thereof.
22. A vented filter assembly as defined in Claim 21 wherein said ridged scrim is folded substantially in half so that said ridges face toward each other and prevent complete surface to surface contact of said folded portions of scrim, with said plurality of channels being provided between said folded portions to carry fluid through said filter pouch.
23. A vented filter assembly as defined in Claim 18 wherein said flow maintenance member has a plurality of channels on both surfaces thereof for carrying fluid through said filter pouch.
24. A vented filter assembly as defined in Claim 18 wherein said gas vent includes an opening through said housing and a hydrophobic membrane filter medium attached to said housing to cover said opening, thereby allowing gas to escape therethrough.
- 40 25. A vented filter assembly as defined in Claim 18 wherein said filter pouch is formed from a hydrophilic membrane filter medium.
26. A vented filter assembly comprising: a closed housing having two fluid passing ports and a passage connecting said ports; a flexible filter pouch in said passage, said pouch having a fluid opening in one end thereof communicating with one of said ports; means within said pouch for preventing the collapse of said pouch on itself to thereby allow the flow of fluid therethrough when fluid passes from said passage through said pouch and into the interior thereof; and a gas vent in said housing adapted to allow gas but not fluid to pass from said passage out of said housing.
27. A vented filter assembly comprising: a closed housing consisting of a pair of flexible sheets sealed together around their peripheries except for a fluid inlet and a fluid outlet, said housing including a passage within connecting said inlet and outlet; a flexible fluid filter pouch having a fluid opening in one end thereof disposed within said passage with said outlet communicating with the interior of said filter pouch through said fluid opening, there by defining an upstream pressure section in the passage between said inlet and said filter pouch and a downstream pressure section in said passage between said filter pouch and
- 5 70 said outlet, said filter pouch comprising a hydrophilic membrane filter medium folded substantially in half and having seal means along two edges adjacent the folded edge and a porous support sheet overlying substantially the entire outer surface of said hydrophilic filter medium, said sheet being folded substantially in half to conform to said folded filter medium; a substantially flat, scrim material disposed within said pouch and folded substantially in half with the folded portions in overlying relationship, said scrim having a plurality of ridges defining a plurality of channels on one surface thereof, said ridged surface of each folded portion facing each other to provide said plurality of channels between said folded portions to channel said fluid to said outlet when said flexible pouch is collapsed against said scrim during fluid flow through said pouch into the interior thereof;
- 20 80 and a gas vent comprising at least one opening through one of said flexible sheets of said housing communicating with said upstream section of said passage and a hydrophobic membrane filter medium attached to the interior surface of said flexible sheet to cover said opening.
- 25 85 28. A vented filter assembly as defined in Claim 27 wherein said hydrophilic filter is a porous polycarbonate film, and said hydrophobic filter is a polyvinylchloride laminated tetrafluoroethylene film, both films having a pore size of about 0.2 microns.
- 90 29. An extension set for use in an administration set for delivering fluid intravenously to a patient-recipient comprising: a filtration device having a fluid inlet opening adapted to receive fluid and a fluid outlet opening adapted to discharge filtered fluid; a connector having a first portion adapted to be mated
- 100 105 with a catheter for intravenous insertions; a length of flexible tubing connecting said outlet opening of said filtration device and a second portion of said connector; and backflow check means in said extension set between said
- 110 115 filtration device and said connector for allowing fluid to flow one-way from said filter through said connector, but for preventing fluid from backflowing in the opposite direction from said one-way flow.
- 120 30. An extension set as defined in Claim 29 wherein said backflow check means comprises a housing having a fluid inlet and a fluid outlet with an internal passage connecting said inlet and outlet; a valve seat associated with said fluid inlet; and movable valve means in said passage operatively responsive to fluid backflow through said outlet into said passage for cooperation with said valve seat to prevent fluid from passing out of said
- 125 130 housing through said inlet.

31. An extension set as defined in Claim  
30 wherein said movable valve means has  
freedom of movement in said passage to  
move towards and away from said inlet,  
5 whereby fluid flowing into said passage  
through said inlet urges said valve means  
away from said inlet to allow fluid to pass  
through said housing, but fluid backflowing  
into said passage through said outlet urges  
10 said valve means towards and into engage-  
ment with said valve seat to cooperate with  
the same for preventing fluid from passing out  
of said housing through said inlet.
32. An extension set as defined in Claim  
15 29 wherein said valve means is a ball.
33. An extension set as defined in Claim  
32 wherein said ball is made of metal.
34. An extension set as defined in Claim  
29 wherein said valve means is a substantially  
20 flat disc.
35. An extension set as defined in Claim  
34 wherein said disc is made of flexible  
material.
36. An extension set as defined in Claim  
25 29 wherein said filtration device further in-  
cludes a gas vent therein adapted to allow gas  
which enters said device through said fluid  
inlet to pass out of said device.
44. A vented filter assembly substantially  
30 as described and shown in the accompanying  
drawings.

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